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Atty. Dkt. No. 056859-0131

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bangalore Eshwar Armita RANI et al.
Title: A PROCESS FOR THE PRODUCTION OF EGG YOLK
ANTIBODIES FOR ORGANOCHLORINE PESTICIDES
Appl. No.: 09/973,199
Filing Date: 10/10/2001
Examiner: Phuong N. Huynh
Art. Unit: 1644

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Declaration Under 37 C.F.R. § 1.132

1. I, Bangalore Eshwar Armita Rani, age 42 years, residing at INDIA, and a citizen of India, do hereby state as follows.

2. I am a Scientist at the Central Food Technological Research Institute, Mysore, India. I graduated in the year 1982 from Bangalore University located at Bangalore, Karnataka, INDIA. I completed my Master's Degree in 1984 from Bangalore University at Department of Zoology, Bangalore, Karnataka, INDIA. Subsequently, I completed my doctoral degree in Zoology from the University of Mysore, Karnataka, India in the year 1991.

3. After completing my doctoral degree, I took up my first assignment as a Lecturer in Zoology with the Department of Studies Zoology, Manasagangothri, University of Mysore, Mysore, Karnataka in the year 1992. After that, I joined the Food Protectants and Infestation Control Department, Central Food Technological Research

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Institute, Mysore, India in year 1993. I am continuing to work with the institute for last 11 years and am presently working on Pesticide Residue Analysis Immunoassay and Toxicology.

4. I am aware of the prosecution history of this case and am in receipt of the final office action issued by U.S. PTO.

5. I believe that the invention of the captioned application is not obvious because one of skill in the art at the time of the invention would not have had a reasonable expectation of the success of the invention. Contrary to the Examiner's position, the development of the Beasley *et al.* Food and Agricultural Immunology (2000) 12, 203-215 immunoassay for hexachlorocyclohexane (HCH) in rabbits, would not be reasonably predictive of the development in the present invention, which relates to the production of egg yolk antibodies that bind to 2,4,5 trichlorophoxyaetic acid. The state of the art is such that because rabbits and chickens are two phylogenetically different animals, success in raising antibodies to one type of small organic molecule in rabbits is not reasonably predictive of being able to raise antibodies to another type of small organic molecules in chickens.

6. Furthermore, rabbit antibodies and chicken antibodies have structural differences that further make it unreasonable to assume that successful antibody production in rabbits will also be successful for chickens. Rabbit antibodies have a molecular weight of 10,000 Daltons, while that of poultry have a molecular weight of 19,000 Daltons. The egg yolk antibodies have three carbohydrate moieties, while the rabbit antibody has only two carbohydrate moieties. The rabbit antibody has a hinge region, while the egg yolk antibodies lack it.

7. I also submit that I have no knowledge of egg yolk antibodies to small organic molecules, let alone pesticides, being successfully produced.

8. One of skill in the art would not have had a reasonable expectation of success of the administration of 1000 µg and 500 µg of the present invention.

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9. The present invention was only achieved after the inventors conducted multiple experiments of varying nature. It is only after several years of hard work involving much human involvement and inventive skills that the inventors have been able to achieve the desired results.

10. The applicants have an understanding with a multinational company to commercialize the device of the instant application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Dated: 25th Feb 2004



BANGALORE ESHWAR AMITA RANI